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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,075	07/29/2003	Dwight H. Warkentin	P-9003.00	5951

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAK

<b>Office Action Summary</b>	<b>Application No.</b> 10/629,075	<b>Applicant(s)</b> WARKENTIN, DWIGHT H.	
	<b>Examiner</b> Kennedy Schaetzle	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-18 and 20 is/are rejected.
- 7) ☒ Claim(s) 2,9 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the coupling of the absolute pressure sensor to an ambient pressure reference unit (claim 2) cannot be found.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 6-8, 10, 11, 13-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson (Pat. No. 6,026,324).

Regarding claim 1 and claims with similar limitations, note col. 7.

Regarding claim 11, the examiner considers a pressure sensor located within the housing in its broadest sense to be coupled to pacing leads (22, 24) extending from the housing.

Regarding claim 17, in order for the microprocessor-based controller of Carlson to operate, it is essential and thus inherent that the instructions be stored on a computer readable media.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson (Pat. No. 6,026,324).

Regarding claims 5 and 12, although Carlson does not explicitly state that the pressure sensor is adapted to be coupled to a defibrillation lead, combined pacer/defibrillator implants are old and widely used to treat a combination of cardiac arrhythmias. To combine the Carlson pacer with a defibrillator in order to provide the most comprehensive and effective treatment would have been seen as an obvious matter of design with the condition of the individual under treatment dictating the need. It should be noted that in the broadest sense, a pressure sensor contained in an implant housing is considered to be coupled to any lead extending from the housing.

***Response to Arguments***

6. Applicant's arguments filed May 13, 2005 have been fully considered but they are not persuasive.

In regards to the objection to the specification, the applicant argues that the coupling of the absolute pressure sensor to an ambient pressure reference unit is supported in paragraph 070 by virtue of the fact that said paragraph refers to "relative" patient data. It is further argued that as the original claims are a part of the specification, agreement between the claim language and the specification is not required as per MPEP 2173.05(e). The examiner disagrees. The phrase "relative patient data" does not provide clear support or antecedent basis for the specific limitation regarding coupling of an absolute pressure sensor to an ambient pressure reference unit. The section of the MPEP that the applicant refers to is not relevant to the situation at hand as it applies to the rejection of claims under §112, 2<sup>nd</sup> paragraph. The examiner has not rejected any claim as being indefinite due to the improper antecedent basis. The applicant is once again referred to 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Regarding the applicant's argument concerning the application of the Carlson reference and the assertion that Carlson does not teach measuring a fluid pressure, the examiner refers the applicant to col. 2, lines 31-38, wherein the accelerometer is recited as transmitting a signal associated with fluid and myocardial acceleration, and where

said transmitted signal is further processed to produce a waveform related to a *pulse pressure within the patient's heart*. Carlson further discloses that prior artisans have measured pulse pressure in a variety of ways, including cardiac catheterization, lead-based pressure sensors, and the use of a piezoelectric pressure sensor mounted on a lead for measuring ventricular systolic pressure (col. 1, lines 35-56). The processed output of the accelerometer is indicative of a measure of developing fluid pressure as discussed further in col. 7, lines 35-53 wherein it is taught that the peaks of Figs. 3-7 correspond to the ejection of blood fluid, and correlate to a measured pulse pressure. Pulse pressure in the context of the Carlson invention clearly relates to fluid pressure.

Regarding the placement of the Carlson pressure sensor in a housing external the heart, the applicant argues that such an arrangement cannot measure pressure, but rather relative movement of the entirety of the heart with respect to the can. It is further argued that Carlson cannot measure "developing fluid pressure" from within a cardiac chamber, and that Carlson specifically teaches away from such measurements. The examiner cannot find any limitation requiring that the measurement of developing fluid pressure be made with a pressure sensor internal to the heart. Adapting a sensor to be coupled to a cardiac chamber does not preclude the use of a sensor located outside of the chamber and spaced therefrom. The assertion that Carlson cannot measure pressure is refuted by the fact that it is explicitly taught that a pressure pulse is measured. Furthermore, the applicant's assertion that Carlson explicitly teaches away from such measurements in col. 1, line 50 to col. 2, line 5, is not agreed with. As discussed above, the applicant's claim does not require the measurement of fluid pressure from within a heart chamber. Carlson does not teach against the measurement of fluid pressure, simply that pressures are preferably measured non-intrusively. Furthermore, a reference is no less anticipatory if, after disclosing the invention, the reference then disparages it (see the "Discussion of the Related Art" section where prior art pressure sensors are discussed then disparaged). The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The prior art was held to anticipate

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the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). See also *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Claimed composition was anticipated by prior art reference that inherently met claim limitation of "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration.).

Regarding the argument concerning the coupling of a pressure sensor to a lead (in an apparent reference to claim 4), the applicant appears to be reading limitations from the specification into the claim when interpreting the meaning of the word "coupling." Lacking any explicit definition in the specification, the examiner must interpret common words in their broadest reasonable sense. The word "coupling" can simply mean "... 1a: to connect for consideration together b: to join for combined effect..." (Merriam-Webster). Since the various elements of the cardiac stimulating device of Carlson are joined to form a single operational system, the examiner considers the elements (including the pressure sensor and the lead) to be coupled together.

#### ***Allowable Subject Matter***

7. Claims 2, 9 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 2, the examiner agrees that there is no suggestion to replace the specific pressure sensor disclosed by Carlson with a pressure sensor that comprises an absolute pressure sensor coupled to an ambient pressure sensor. Carlson teaches that the accelerometer allows one to determine pulse pressure without having to utilize an intrusive type sensor. Related comments apply to claims 9 and 19.

#### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
August 7, 2005

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER  
8/7/05